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# **Automated Control of Endotracheal Tube Cuff Pressure during Simulated Flight**



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## 1.0 SUMMARY

Successful mechanical ventilation requires that the airway be controlled by an endotracheal tube (ETT) with an inflatable cuff to seal the airway. Aeromedical evacuation represents a unique challenge in which to manage ETT cuffs. We evaluated three methods of automatic ETT cuff pressure adjustment during changes in altitude in an altitude chamber. Size 7.5- and 8.0-mm ETTs that are currently included in the Critical Care Air Transport Team allowance standard were used for the evaluation. Three automatic cuff pressure controllers—Intellicuff, Hamilton Medical; Pyton, ARM Medical; Cuff Sentry, Outcome Solutions—were used to manage cuff pressures. The fourth group had cuff pressure set at sea level without further adjustment. Each ETT was inserted into a tracheal model and taken to 8,000 feet and then to 16,000 feet at 2,500 ft/min. Baseline cuff pressure at sea level was approximately 25 cmH<sub>2</sub>O. Results: Mean cuff pressure at both altitudes with both size ETTs was as follows: Control arm 141 ± 64 cmH<sub>2</sub>O; Pyton 25 ± 0.8 cmH<sub>2</sub>O; Cuff Sentry 22 ± 0.3 cmH<sub>2</sub>O; Intellicuff 29 ± 6.6 cmH<sub>2</sub>O. The mean time that cuff pressure was > 30 cmH<sub>2</sub>O using Intellicuff at both altitudes was 2.8 ± 0.8 minutes. Pressure differences from baseline in the control arm and with Intellicuff were statistically significant. Cuff pressure with the Cuff Sentry tended to be lower than indicated on the device. Mean cuff pressures were within the recommended range with all three devices. Intellicuff had difficulty regulating the cuff pressure initially with increases in altitude but was able to reduce the pressure to a safe level during the stabilization period at each altitude. The Pyton and Cuff Sentry allowed the least variation in pressure throughout the evaluation, although the Cuff Sentry set pressure was less than actual pressure.

## 2.0 BACKGROUND

Management of the critically ill, mechanically ventilated casualty during aeromedical transport presents a number of challenges. Noise, vibration, low light, space constraints, limited resources and hypobarism conspire to further complicate a difficult mission [1,2]. Hypobaric conditions reduce the partial pressure of oxygen in ambient air and impact gas trapped in closed spaces. This includes gas trapped in anatomic spaces (pleural, ocular, etc.) as well as within devices (endotracheal tube cuffs, ventilators, computers).

Our group has previously demonstrated that management of the endotracheal tube (ETT) cuff during ascent, cruising altitude, and descent can result in large changes in the pressure and volume of the ETT cuff [3]. At ascent, these changes can result in damage to the tracheal mucosa and long-term complications including tracheal stenosis. During descent, reductions in cuff volume leads to aspiration of secretions from the oropharynx that are implicated in the development of ventilator-associated pneumonia [4].

Clinically important changes in cuff pressures have been seen in fixed wing and rotor wing environments [5-12]. In recent years, automated control of ETT cuff pressure has been accomplished in the intensive care unit (ICU) with stand-alone devices as well as those integral to a ventilator [13,14]. We hypothesized that closed loop control of ETT cuff pressure during flight might provide a solution for this clinical conundrum.

## 3.0 METHODS

### 3.1 Devices

The Intellicuff system is integral to the G5 mechanical ventilator (Hamilton Medical, Reno, NV). On the user interface of the ventilator, the Intellicuff program was opened and the target cuff pressure was entered using a numeric keypad (Figure 1). Tubing going from the device to the pilot balloon of the ETT cuff is used to monitor cuff pressure and to add or release air to maintain the set pressure.

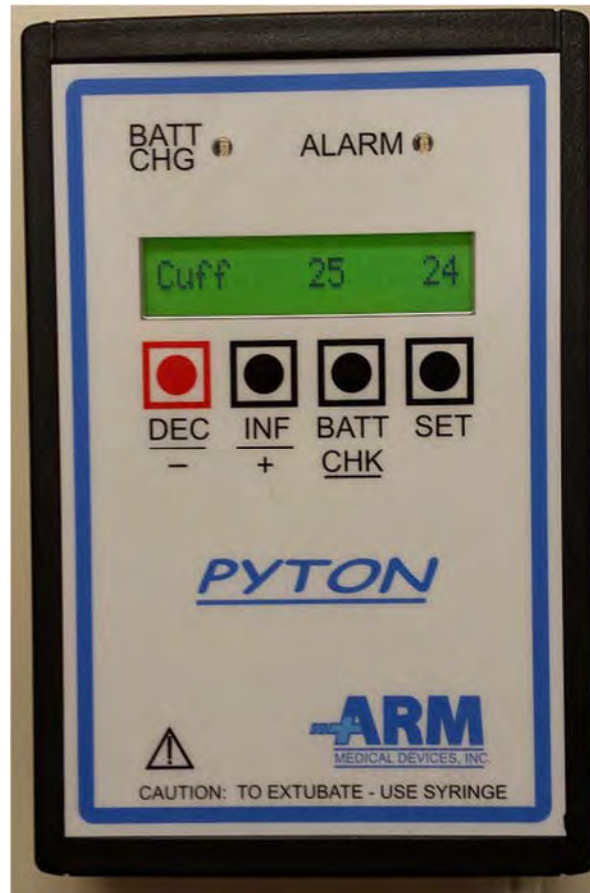


Figure 1. Intellicuff system software.

The Pyton cuff pressure regulator is self-contained with a digital numeric readout of the set and actual pressure displayed (Figure 2). It operates in much the same way as Intellicuff without it being attached to a specific ventilator. Tubing attaches to the device and to the ETT pilot balloon and the device manipulates cuff pressure based on set pressure using a small compressor in the control unit.

The Cuff Sentry uses a mechanical manometer to monitor cuff pressure (Figure 3). The device was attached to an oxygen flow meter and tubing attached to the device and to the ETT pilot balloon. A spring-loaded pop-off valve releases air when cuff pressure exceeds the set pressure setting or the gas supplied from the flow meter adds gas to the ETT cuff if the pressure falls below the set pressure. This system requires a continuous flow of gas at 0.5-2.0 L/min. The ETT cuff was inflated with air to a pressure of 25 cmH<sub>2</sub>O in the control model using a cuff pressure manometer (Rusch Endotest, Teleflex Incorporated, Limerick, PA) and not manipulated again.





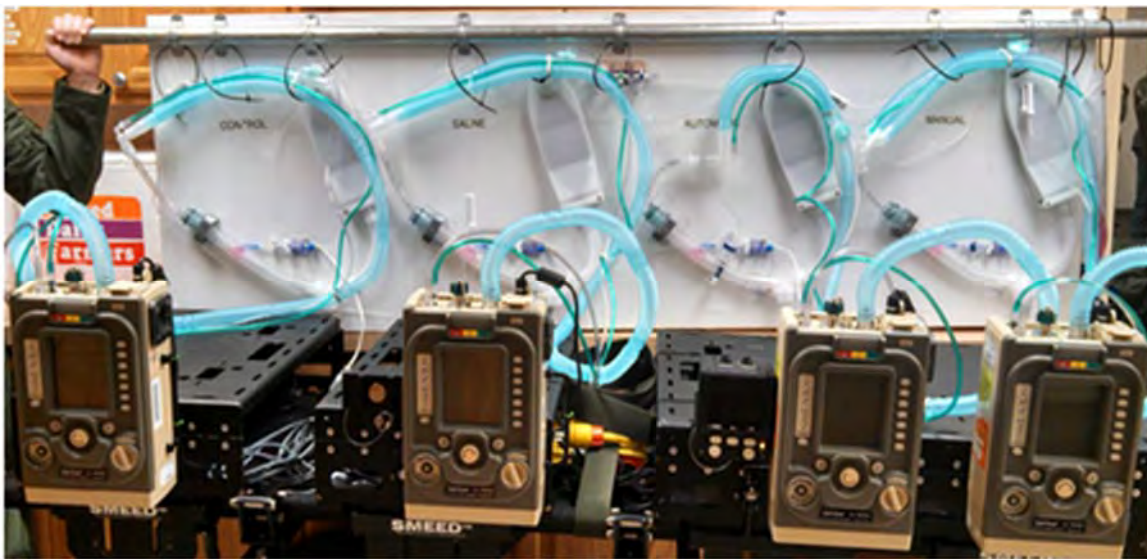
**Figure 2. Pyton cuff pressure regulator.**



**Figure 3. The Cuff Sentry system.**

### 3.2 Procedure

The study was conducted in an altitude chamber at Wright-Patterson Air Force Base, Dayton, Ohio. Size 7.5-mm and 8.0-mm ETTs (Hi/Lo Oral/Nasal Tracheal Tube, Mallinckrodt, Covidien, Mansfield, MA) that are currently included in the Critical Care Air Transport Team allowance standard were used for the evaluation. Three commercially available and Food and Drug Administration approved automatic cuff pressure adjustment devices (Intellicuff, Hamilton Medical, Reno, NV; Pyton, ARM Medical, Bristol, CT; Cuff Sentry, Outcome Solutions, Mocksville, NC) were used to manage the cuff pressures with each ETT. Currently the Intellicuff system is integral to the Hamilton ICU ventilator, while the other two devices are stand-alone products. The fourth group of ETTs had the cuff pressure measured by the respiratory therapist and adjusted manually at sea level and did not have the pressure manipulated throughout each evaluation of the automatic devices and served as the control. Each flight used a new ETT for each experimental condition. Each ETT was lubricated with Surgilube (Fougera Pharmaceuticals Inc., Melville, NY) and inserted into a model of the upper airway (Laerdal Medical, Wappingers Falls, NY) with an inner diameter of 22 mm. A portable ventilator (Model 731, Impact Instrumentation, West Caldwell, NJ) was attached to each ETT and each tracheal model was attached to a test lung (Adult 190 1 Liter, Maquet, Rastatt, Germany). To simulate a clinical environment, each model was ventilated using ventilator settings of respiratory rate of 12, tidal volume of 450 mL, positive end expiratory pressure of 5 cmH<sub>2</sub>O, and a fraction of inspired oxygen of 0.21. Figure 4 shows the experimental model.



**Figure 4. Experimental model.**

The pilot balloon of each ETT cuff was connected to a physiological pressure transducer (Edwards TruWave Disposable Pressure Transducer, Edwards Lifesciences, Irvine, CA) and data logger (Sparx Engineering LLC, Manvel, TX) via 3-way stopcock. Cuff pressure was monitored throughout the flight and recorded to a personal computer for later analysis. The models were taken to 8,000 feet and then to 16,000 feet at 2,500 ft/min. Pressure was allowed to stabilize for

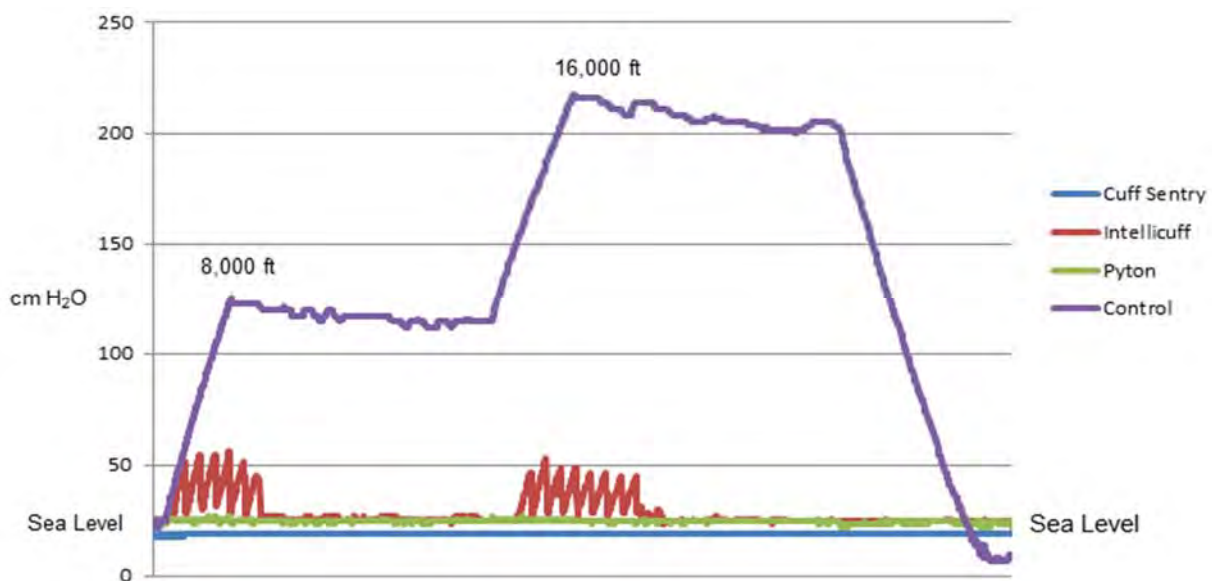
10 minutes at each altitude. The model was then returned to sea level at 2,500 ft/min. The cuff pressure set at sea level was approximately 25 cmH<sub>2</sub>O as set with each device and by using a cuff manometer in the control arm. Two different Cuff Sentry devices were used to test the accuracy between the pressures indicated by the mechanical gauge of the device as compared to pressure measured by the data logger. Cuff pressures were continuously recorded every second to a data logger. Each test was completed a minimum of two times. A t-test was used to determine statistical significance ( $p < 0.5$ ) between initial cuff pressure and actual pressure at altitude.

## 4.0 RESULTS

The Python was able to maintain cuff pressures within the target 20-30 cmH<sub>2</sub>O using both size ETTs, at each altitude, during all three simulated flights. The mean cuff pressure at both altitudes was  $24 \pm 1.0$  cmH<sub>2</sub>O and  $25 \pm 0.8$  cmH<sub>2</sub>O using 7.5 and 8.0 ETTs, respectively. The Cuff Sentry was able to keep the cuff pressure within the target pressure range ( $22 \pm 0.8$  cmH<sub>2</sub>O) using the 7.5 ETT but was just below the range ( $19 \pm 0.7$  cmH<sub>2</sub>O) using the 8.0 ETT.

Mean cuff pressure with Intellicuff was within the target range using both size ETTs and at both altitudes ( $29.7 \pm 1.1$  cmH<sub>2</sub>O) except during the first flight at 8,000 feet with both size ETTs ( $34 \pm 8$  cmH<sub>2</sub>O and  $35 \pm 15$  cmH<sub>2</sub>O). Intellicuff had difficulty maintaining the target pressure with initial changes in altitude but eventually stabilized near the baseline pressure at both altitudes. The mean time that Intellicuff allowed cuff pressure to be  $> 30$  cmH<sub>2</sub>O at all test conditions at each altitude ranged from  $2.4 \pm 0.7$  minutes to  $3.4 \pm 0.5$  minutes.

Baseline pressure at sea level and pressure at sea level after the flights were within 2 cmH<sub>2</sub>O with all three automatic devices. Peak cuff pressure in the control arm ranged from  $126 \pm 1.7$  cmH<sub>2</sub>O to  $224 \pm 19.7$  cmH<sub>2</sub>O with mean pressure range of  $106 \pm 30$  cmH<sub>2</sub>O to  $177 \pm 62$  cmH<sub>2</sub>O). Figure 5 shows continuous cuff pressure measurements with the three devices being tested plus the control (no adjustment) during a simulated flight using an 8.0 ETT.



**Figure 5. Continuous cuff pressure measurements with the three devices being tested plus the control (no adjustment) during a simulated flight using an 8.0 ETT.**

Peak cuff pressures varied widely in the control and Intellicuff study arms but not in the Pyton and Cuff Sentry arms. Table 1 shows the average (standard deviation [SD]) peak pressures for three simulated flights at all test conditions. Measured pressures before, during, and after the flights (18-24 cmH<sub>2</sub>O) were always less than the pressure indicated on the Cuff Sentry manometer (~25 cmH<sub>2</sub>O). Table 2 depicts the duration of time with normal cuff pressure (20-30 cmH<sub>2</sub>O), low pressure < 20 cmH<sub>2</sub>O, and high cuff pressures 31-50 cmH<sub>2</sub>O and > 50 cmH<sub>2</sub>O with each device at both altitudes with each size ETT.

**Table 1. Average Maximum Pressure (SD) at Each Altitude with 7.5 and 8.0 ETT, Each Adjustment Method, at All Study Conditions**

Controller	Baseline		8,000 ft		16,000 ft		Sea Level after Flight	
	7.5	8.0	7.5	8.0	7.5	8.0	7.5	8.0
Control	25 (1.2)	24 (2.0)	124 (12.7) <sup>a</sup>	126 (1.7) <sup>b</sup>	217 (20.1) <sup>c</sup>	224 (19.7) <sup>b</sup>	13 (4.6)	8 (0.6) <sup>b</sup>
Intellicuff	26 (1.5)	25 (0.7)	54 (0.6) <sup>a</sup>	68 (17.0) <sup>c</sup>	51 (1.7) <sup>b</sup>	53 (0.7) <sup>c</sup>	26 (1.5)	27 (0.7)
Pyton	25 (1.2)	24 (0.6)	27 (0.6)	27 (0.6)	27 (0.6)	27 (0.6)	24 (0.6)	23 (1.2)
Cuff Sentry	23 (0.6)	19 (0.7)	24 (1.2)	19.5 (0.7)	24 (1.2)	19.5 (0.7)	23 (0.6)	19 (0.7)

<sup>a</sup>p < 0.001, as compared to baseline pressure.

<sup>b</sup>p < 0.01.

<sup>c</sup>p < 0.05.

**Table 2. Duration in Minutes ± SD that Cuff Pressure was within Each of the Pressure Ranges and Percentage of Total Time in Those Ranges with Each Device**

Pressure Range (mmHg)	Intellicuff		Cuff Sentry		Pyton	
	7.5 ETT	8.0 ETT	7.5 ETT	8.0 ETT	7.5 ETT	8.0 ETT
<20	0	0	0	12.5 ± 0.3 (100%)	0	0
20 – 30	10.4 ± 0.6 (79%)	9.6 ± 0.6 (77%)	13.2 ± 0.5 (100%)	0	13.2 ± 0.5 (100%)	12.5 ± 0.3 (100%)
31 – 50	2.6 ± 0.5 (20%)	2.4 ± 1.1 (19%)	0	0	0	0
> 50	0.2 ± 0.2 (1%)	0.4 ± 0.4 (3%)	0	0	0	0

## 5.0 DISCUSSION

This is the first evaluation of automated ETT cuff pressure devices at altitude. Our data demonstrate that automatic control of cuff pressure is more consistent than manual methods and less likely to allow over or under inflation [3]. There were differences between devices, with the two stand-alone devices being superior at maintaining cuff pressure compared to the device integral to the Hamilton ventilator. Our data confirm the findings of many others regarding the impact of altitude on cuff pressures, with minor changes in altitude resulting in significant increases [5-12].

Routine cuff pressure measurement is a standard of care in ICUs around the world [4]. Maintenance of the appropriate cuff pressure is necessary to prevent both overinflation and related mucosal damage as well as underinflation promoting fluid leakage around the cuff, which is associated with pneumonia. Aeromedical transport represents an added challenge to cuff pressure management. On the ground, a cuff pressure of 25 cmH<sub>2</sub>O rapidly changes with ascent [3]. At the time of ascent, caregivers are typically seated for safety, preventing active manipulation of cuff pressure. At a routine cruising altitude of 8,000 feet, cuff pressure may exceed 80 cmH<sub>2</sub>O. If the cuff is adjusted by removing air at altitude, the converse problem

occurs during descent. A pressure of 25 cmH<sub>2</sub>O rapidly changes with descent to below 10 cmH<sub>2</sub>O, allowing fluid above the cuff to readily move into the lower respiratory tract. As with ascent, caregivers are unable to manipulate cuff pressure during descent owing to safety concerns related to landing. These clinical conundrums appear to be easily solved by automated cuff pressure management. Implementation in the aircraft will require the purchase of new technology and the appropriate airworthiness approvals.

All three devices managed cuff pressure in the desired range in a fashion far superior to manual manipulation. The Hamilton Intellicuff demonstrated a period of instability in the first several minutes of ascent. Intellicuff uses a rule-based algorithm to adjust pressure based in the absolute pressure. Across the normal range (<67.5 mmHg), pressure is adjusted every 30 seconds. Above this pressure, adjustments are made every 2 seconds. These methods of pressure adjustments would explain the kind of oscillations seen in the pressure waveform. A more rapid adjustment rate would seem to solve this problem; however, in routine ICU care, adjustments made too rapidly can result in wide swings in cuff pressure associated with coughing and patient position change and can lead to underinflation and aspiration of secretions [15,16].

The Cuff Sentry device maintained a constant pressure, but operation of the device is problematic for aeromedical transport. Pressure is maintained by balancing gas flow (air or oxygen) from a flowmeter and use of a spring-loaded pressure release valve. A continuous flow of gas, particularly of oxygen, into the environment may increase the risk of fire and depletes finite resources. The system is mechanical in nature and has no alarms to alert of malfunction, loss of pressure, or occlusion. These features make this device undesirable for aeromedical use despite performance as intended.

The Pyton device maintained a constant pressure throughout flight and was the most reliable and consistent device tested. The unit is self-contained and would require mounting to the current patient movement items and assurance of electrical power. The size of the control unit is moderate, about one-third the size of the current ventilator. Incorporation of this technology into existing ventilators might prove useful.

The use of automated cuff pressure management in the ICU is not routine. Early literature demonstrates the ability of these techniques to maintain cuff pressure in the desirable, safe range; changes in tracheal damage and reductions in ventilator-associated pneumonia have not been reported in all cases.

## 6.0 CONCLUSIONS

Our study has several limitations, chief of which is that we did not make these measurements in human subjects. The model was chosen to represent the shape and size of the trachea and allow some dispensability as would the human trachea. We lubricated cuffs to more accurately reproduce clinical conditions and to improve seal in the tracheal model. The impact of different size and shaped tracheas, different ratios of ETT diameter to tracheal diameter, and varying flight patterns might all yield different results. Our data are applicable to fixed wing aeromedical transport, and changes in rotor wing flight may be different owing to lower altitudes and flight patterns. Our model also does not include vibration, which might impact pressure measurements. While the changes in cuff pressure at altitude are well known, an increase in long-term airway complications (e.g., tracheal stenosis) has not been identified in subjects undergoing aeromedical transport.



Changes in ETT cuff pressure at altitude are well described and represent an ongoing concern to aeromedical transport of mechanically ventilated patients. During a simulated flight, the devices tested were far superior to manual control for maintaining a safe and consistent cuff pressure. Implementation in aeromedical transport should be seriously considered.

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## **LIST OF ABBREVIATIONS AND ACRONYMS**

<b>ETT</b>	endotracheal tube
<b>ICU</b>	intensive care unit
<b>SD</b>	standard deviation